UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.* Case No. 18-op-45090	MDL No. 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster

DECLARATION OF CHARLES C. LIFLAND IN SUPPORT OF THE MANUFACTURER DEFENDANTS' JOINT MOTION TO DISMISS PLAINTIFFS' SECOND AMENDED COMPLAINT

I, Charles C. Lifland, declare as follows:

1. I am a partner at the law firm of O'Melveny & Myers LLP and counsel of record for Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc, and Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc., in the above-captioned matter. I am a member in good standing of the State Bar of California. I submit this declaration in support of the Manufacturer Defendants' Joint Motion to Dismiss Plaintiffs' Second Amended Complaint. I have personal knowledge of the following facts and, if called and sworn as a witness, could and would testify competently thereto.

2. Attached hereto as **Exhibit A** is a true and correct copy of a Letter from the Food and Drug Administration ("FDA") to Physicians for Responsible Opioid Prescribing ("PROP"),

dated September 10, 2013, *available at* https://www.regulations.gov/document?D=FDA-2012-P-0818-0793 (last accessed May 25, 2018).

3. Attached hereto as **Exhibit B** is a true and correct copy of the complaint filed in *State of Ohio ex rel. Mike DeWine v. Purdue Pharma L.P. et al.*, Case No. 2017 Cl 261 (Ohio Ct. Com. Pl. May 31, 2017).

4. Attached hereto as **Exhibit C** is a true and correct copy of the prescription drug label for NUCYNTA® ER approved by the FDA as revised December 2016, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/200533s014lbl.pdf (last accessed May 25, 2018).

5. Attached hereto as **Exhibit D** is a true and correct copy of the prescription drug label for OXYCONTIN® approved by the FDA as revised December 2016, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022272s034lbl.pdf (last accessed May 25, 2018).

6. Attached hereto as **Exhibit E** is a true and correct copy of the prescription drug label for ACTIQ® approved by the FDA as revised December 2016, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020747s043s044lbl.pdf (last accessed May 25, 2018).

7. Attached hereto as **Exhibit F** is a true and correct copy of the prescription drug label for FENTORA® approved by the FDA as revised December 2016, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021947s024s025lbl.pdf (last accessed May 25, 2018).

8. Attached hereto as **Exhibit G** is a true and correct copy of the prescription drug label for SUBSYS® approved by the FDA as revised December 2016, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/202788s016lbl.pdf (last accessed May 25, 2018).

9. Attached hereto as **Exhibit H** is a true and correct copy of the prescription drug label for KADIAN® approved by the FDA as revised December 2016, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020616s057lbl.pdf (last accessed May 25, 2018).

10. Attached hereto as **Exhibit I** is a true and correct copy of the prescription drug label for OPANA® ER approved by the FDA as revised December 2016, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/201655s021lbl.pdf (last accessed May 25, 2018).

11. Attached hereto as **Exhibit J** is a true and correct copy of the prescription drug label for EXALGO® approved by the FDA as revised September 2016, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021217s019lbl.pdf (last accessed May 25, 2018).

12. Attached hereto as **Exhibit K** is a true and correct copy of an FDA press release entitled *FDA to Approve Shared System REMS for TIRF Products*, dated December 29, 2011, *available at* https://www.prnewswire.com/news-releases/fda-to-approve-shared-system-rems-for-tirf-products-136382168.html (last accessed May 25, 2018).

13. Attached hereto as **Exhibit L** is a true and correct copy of the Transmucosal Immediate Release Fentanyl ("TIRF") Risk Evaluation and Mitigation Strategy ("REMS"),

available at https://www.accessdata.fda.gov/drugsatfda_docs/rems/TIRF_SS_2015-12-21_REMS_FULL.pdf (last accessed May 25, 2018).

I declare under penalty of perjury that the foregoing is true and correct. This Declaration was executed in Los Angeles, California on May 25, 2018.

/s/ Charles C. Lifland

Charles C. Lifland

O'MELVENY & MYERS LLP
400 S. Hope Street
Los Angeles, CA 90071
Telephone: (213) 430-6000
Facsimile: (213) 430-6407
clifland@omm.com

Attorney for Defendants Janssen Pharmaceuticals, Inc., Johnson & Johnson, Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc., and Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on May 25, 2018, a copy of the foregoing **Declaration of Charles C. Lifland in Support of the Manufacturer Defendants' Joint Motion to Dismiss Plaintiffs' Second Amended Complaint** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

Dated: May 25, 2018

/s/ Charles C. Lifland

Charles C. Lifland
O'MELVENY & MYERS LLP
400 S. Hope Street
Los Angeles, CA 90071
Telephone: (213) 430-6000
Facsimile: (213) 430-6407
clifland@omm.com

Attorney for Defendants Janssen Pharmaceuticals, Inc., Johnson & Johnson, Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc., and Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.